

REMARKS

Formal Matters

Claims 1-45 are pending in the application. A restriction requirement has been made and responded to herein, above.

Claims 1, 6, 9, and 13 are amended. Claims 5, 8, and 11 are canceled without prejudice to later prosecution. Support for the amendments is found throughout the originally filed specification at, for example, page 12, lines 21-23 and lines 28-30; page 15, lines 3-5; the last paragraph on page 15, bridging pages 15-16; the last paragraph on page 29, bridging pages 29-30; and page 56, lines 2-13. No new matter is added by the amendment.

Applicants respectfully submit that the claims are in condition for allowance, which action is respectfully requested.

RESPONSE TO RESTRICTION REQUIREMENTS:

Restriction and Further Restriction Requirements

In the outstanding Office Action, the Examiner has required restriction of the claims to one of the following groups under 35 U.S.C. §121:

- I. Claims 1-30, drawn to a method of detecting high grade dysplasia of a tissue sample by establishing the expression profile of at least eight genes, and comparing to a baseline profile, wherein the expression increases 1.5 fold indicates hyperplasia, classified in class 536, subclass 24.5.
- II. Claims 31-36, drawn to a kit that comprises a microarray comprising nucleic acid probes, classified in class 536, subclass 24.31.
- III. Claims 37-45, drawn to a method of detecting cancer in a patient by establishing level of expression of a plurality of genes and compare to the baseline expression, classified in class 435, subclass 91.2.

In response to the restriction requirement, **Applicants hereby elect, with traverse, the claims of Group I (claims 1-30) for further prosecution.**

Further Restriction

On page 3 of the Office Action, the examiner requires further restriction of the elected claim group, suggesting that each gene or combination of genes is patentably distinct because they are unrelated sequences. In response to the further restriction requirement, **Applicants hereby elect, with traverse, the five genes listed below with their corresponding SEQ ID NOs as requested by the examiner:**

AGR2 (SEQ ID NO:3),
TM7SF1 (SEQ ID NO:13),
MAT2B (SEQ ID NO:17),
SLNAC1 (SEQ ID NO:23), and
TCF4 (SEQ ID NO:43).

Applicants point to the claim amendments provided herein, in which the claims are amended to recite a method of detecting high-grade dysplasia (HGD) by establishing the level of expression in the test tissue sample of the five genes listed above.

Traversal of the requirements

Applicants respectfully traverse the restriction requirement and election of species requirement because the Office has not demonstrated any burden upon it to search all groups. (See MPEP §803, second full paragraph: "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."). Applicants request reconsideration of, at least, the further restriction requirement.

The restriction requirements are improper at this time. However, should they be maintained, Applicant requests examination of the elected subject matter on the merits.

Applicant expressly reserves the right under 35 U.S.C. §121 to file one or more divisional applications directed to the non-elected subject matter, as well as any other matter disclosed in the present application which is not encompassed by the elected claims, during the pendency of the present application or an application claiming priority from this application.

Applicants respectfully submit that the claims are in condition for allowance, which action is respectfully requested.

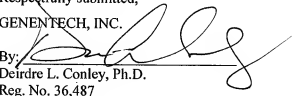
If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Applicants believe that this document is timely submitted and that no fees are due. In the unlikely event that the transmittal letter is separated from this document and the U.S. Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Director to charge the cost of such petitions and/or other fees due in connection with the filing of this.

Respectfully submitted,
GENENTECH, INC.

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